Dated: August 22, 1985.

John M. Taylor,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 85-20730 Filed 8-29-85; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 85E-0296]

Determination of Regulatory Review Period for Purposes of Patent Extension; New Jersey Meniscal Bearing Knee Replacement

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: Food and Drug Administration (FDA) has determined the regulatory review period for the New Jersey Meniscal Bearing Knee Replacement and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESS: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James C. Shehan, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) generally provides that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under that act, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the New Jersey Meniscal Bearing Knee Replacement. This patented product, which consists of the Rotating Platform of the New Jersey Total Knee System (PM30055) and the Sliding Meniscal Bearing of the New Jersey Total Knee System (PM30055/S2), is indicated for cemented use in cases of osteoarthritis and rheumatoid arthritis. Based on this recent approval, DePuy, Inc., has applied for patent term restoration.

FDA has determined that the applicable regulatory review period for the New Jersey Meniscal Bearing Knee Replacement is 1,701 days. Of this time, 1,095 days occurred during the testing phase of the regulatory review period, while 606 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation was begun: August 16, 1980.

The applicant claimed July 14, 1980, as the date which commenced the testing phase. FDA received the application for an investigational device exemption on July 17, 1980. Thirty days after this application was received, it was automatically approved under 21 CFR 812.30(a)(1) on August 16, 1980.

2. The date an application was initially submitted under section 515 of the Federal Food, Drug, and Cosmetic Act: August 16, 1983.

The applicant claimed that the premarket approval applications for the product (PM30055 and PM30055/S2) were submitted on August 12, 1983. However, FDA received the application on August 16, 1983.

3. The date the application was approved: April 12, 1985.

The applicant claimed that its product was approved on April 25, 1985. FDA has determined, however, that premarket approval application (PM30055) and its supplement (PM30055/S2), which cover both parts of the New Jersey Meniscal Bearing Knee Replacement, were approved on April 12, 1985.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 90 days of patent extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 29, 1985, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interrested person may petition FDA, on or before February 26, 1986, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 98-857, Part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the document number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 28,1985.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 85-20936 Filed 8-29-85; 8:45 am]

BILLING CODE 4160-01-M

Health Resources and Services Administration

Redesignation of Illinois Health Service Areas 7 and 8

AGENCY: Health Resources and Services Administration, Public Health Service, HHS.

ACTION: On July 25, 1985 a Notice was published in the **Federal Register** (50 FR 30301) annoucing the Secretary's decision to redesignate Illinois health service areas 7 and 8. The effective date was to have been September 13, 1985. Subsequent to that announcement an action was filed in the U.S. District Court, District of Columbia, seeking to have the Secretary's area redesignation decision set aside. In order to allow that litigation to proceed in an orderly manner, the Department has agreed to postpone the effective date until October 15, 1985.

FOR FURTHER INFORMATION CONTACT: John F. Belin, Director, Division of Agency Operations and Management, OHP, BHMORD, 5600 Fishers Lane, Room 9A-19, Rockville, Maryland 20857, 301-443-6680.